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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,805

01/21/2004

Robert Niecestro

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/761,805	<b>Applicant(s)</b> NIECESTRO ET AL.	
	<b>Examiner</b> Kevin E. Weddington	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15, 16 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 24-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16 and 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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Claims 1-12, 15, 16 and 19-28 are presented for examination.

Applicants' request for continued examination, amendment and response filed December 31, 2007 have been received and entered.

Accordingly, the rejection made under 35 USC 112, second paragraph as set forth in the previous Office action dated September 28, 2007 at page 2 is hereby withdrawn.

Accordingly, the rejection made under 35 USC 102(e) as being anticipated by Phillips (6,645,988 B2) as set forth in the previous Office action dated September 28, 2007 at pages 2-4 is hereby withdrawn because the Phillips reference does not teach the applicants' proton pump inhibitor layer is a granule.

Claims 24-28 are withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 15, 16 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (6,645,988 B2) in view of Shimizu et al. (6,328,994 B1).

Phillips teaches pharmaceutical preparations comprising proton pump inhibitors such as substituted benzimidazoles, wherein the solid dosage form is not enteric coated (see the abstract). Note particular to column 8, lines 15-10 states the proton pump inhibitor (PPI) is combined with a buffering agent and can be formulated into a tablet, suspension tablet, chewable tablet, capsule, two-part tablet or capsule (multi-layered), pellets and granules. Also the formulation can include flavoring agents (a taste masking agent). Column 11, lines 35-54 states the buffering agents (same as antacids) are not limited to sodium, magnesium, aluminum or calcium salts of hydroxides, carbonates, sulfates, bicarbonates or silicates (also see column 14,

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lines 47-54). Column 16, lines 16-37 shows the processes of the dry granulation and wet granulation. Note particular to column 47, lines 34-68 and column 48, lines 1-21 shows the amino acids (same as alkaline agents) can be also employed as buffering agents (buffers). Note the amino acids include lysine and arginine. Finally, Phillips teaches in column 75; claim 1, which the PPI are omeprazole, lansoprazole, pantoprazole, pariprazole, leminoprazole, salts, enantiomers, isomers or derivatives.

The instant invention differs from the cited reference in that the cited reference does not teach the proton pump inhibitor layer is in granule form. However, the secondary reference, Shimizu et al. (6,328,994 B1) teaches multi-layered tablets containing a proton pump inhibitor layer in granule form. Note column 13, lines 1-8 states the use of water-soluble and water-insoluble polymers such as HPC (hydroxymethyl cellulose) or HPMC (hydroxypropylmethyl cellulose), applicants' preferred polymers.

Clearly, one skilled in the art would have assumed substitution of the PPI layer of Phillips with the PPI granule of Shimizu et al., would achieve the same results in the absence of evidence to the contrary.

Claims 1-12, 15, 16 and 19-23 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

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